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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,426	02/18/2004	David J. Jorgenson	P-8050.05	3045
27581	7590	10/25/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			HOLMES, REX R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,426

Applicant(s)

JORGENSEN ET AL.

Examiner

Rex Holmes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4-9, 11, 12, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10, 13, 14 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/18/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/18/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 4-9, 11-12 and 15-16 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/05/2006.
2. Applicant's election with traverse of Embodiment 1 of Group I, with claims 1 and 3 readable thereon, and Embodiment 10 of Group II and Embodiment 11 of Group III with claims 13 and 14 readable thereon, in the reply filed on 09/05/2006 is acknowledged. The traversal is on the ground(s) that the new claim 17 renders the restriction moot. This is not found persuasive because the addition of claim 17, which claims all of the embodiments of Group I, does not correct that fact that the application is directed to multiple patentably distinct species. There is clearly a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction were not required. For example each of the embodiments of Group I, require different sensors and programs to compute and determine each of the embodiments.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cinbis et al. (U.S. Pat. 5,897,577 hereinafter "Cinbis").

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4. Regarding claims 1-3 and 17-18, Cinbis discloses a pacing lead impedance monitoring circuit for use in an implantable medical device designed to collect lead impedance data (Col. 5, 56-65), stimulation threshold data (Col. 2, ll. 21-32), and other data that may be non-physiological data (Col. 8, ll. 8-16). Cinbis further discloses that once it is determined that the leads are no longer functional a signal is created to indicate the status (Col. 9, ll. 5-9).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made:

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cinbis et al. (U.S. Pat. 5,897,577 hereinafter "Cinbis") as applied to claim 1 above, and further in view of Juran et al. (U.S. Pat. 6,016,447 hereinafter "Juran").

8. Regarding claim 10, Cinbis discloses the lead status monitoring system as discussed in detail above, but does not disclose a time from implant source. However, Juran discloses a pacemaker that includes a time from implant source and states that the device may use the implant time to trigger various therapy programs automatically. (Col. 4, ll. 41-49 & Col. 5, ll. 50-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made have modified the lead status monitoring system as taught by Cinbis with the time from implant source as disclosed by Juran in order to keep track of the time since implant to determine time decay and to base and automatically adjust the pacing based on pre-measured decay.

9. Claims 13-14 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cinbis as applied to claim 2 above, and further in view of Dutcher et al. (U.S. Pat. 4,140,131 hereinafter "Dutcher").

10. Regarding claims 13-14 and 19-20, Cinbis discloses the lead status monitoring system as discussed in detail above, but does not explicitly disclose that finds a biological interface issue, explicitly a myocardial perforation. However, Dutcher discloses a stimulation-warning device where impedance level detectors determine lead rupture (Col. 6, ll. 14-22; Fig. 1A, 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the lead status monitoring system as taught by Cinbis with the rupture detection system as

taught by Dutcher in order to determine lead failure by determining the proper placement of the leads before application of the stimulation.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Prutchi et al. (U.S. Pat. 6,141,585) discloses the use of the impedance to characterize tissue interfaces.
- b. Cinbis et al. (U.S. Pat. 5,897,577) discloses a lead impedance status monitor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rex Holmes


George Evanisko

Primary Examiner

10/20/06